



[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[NRC-2019-0164]

Information Collection: Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, "Medical Use of Byproduct Material."

DATES: Submit comments by **[INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2019-0164**. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- **Mail comments to:** David Cullison, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; e-mail: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID **NRC-2019-0164** when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to <https://www.regulations.gov> and search for Docket ID **NRC-2019-0164**. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID **NRC-2019-0164** on this Web site.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The supporting statement and burden spreadsheet are available in ADAMS under Accession Nos. ML19344D378 and ML19344D379

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

- **NRC's Clearance Officer:** A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; e-mail: Infocollects.Resource@nrc.gov.

B. Submitting Comments

Please include Docket ID **NRC-2019-0164** in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* 10 CFR part 35, "Medical Use of Byproduct Material."
2. *OMB approval number:* 3150-0010.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* Reports of medical events, doses to an embryo/fetus or nursing child, or leaking source are reportable on occurrence. A specialty board certifying entity desiring to be recognized by the NRC must submit a one-time request for recognition and infrequently revise the information.
6. *Who will be required or asked to respond:* Physicians and medical institutions holding an NRC license authorizing the administration of byproduct material or radiation from this material to humans for medical use. A specialty board certification entity desiring to have its certifying process and board certificate recognized by NRC.
7. *The estimated number of annual responses:* 299,266 (292,182 reporting responses + 7,019 recordkeepers + 65 third party disclosure responses).
8. *The estimated number of annual respondents:* 7,021 (856 NRC licensees + 6,163 Agreement State licensees + 2 specialty board certification entity).
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 1,166,694 hours (69,391 reporting + 1,097,177 recordkeeping + 127 third party disclosure).
10. *Abstract:* 10 CFR part 35, "Medical Use of Byproduct Material," contains NRC's requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. Part 35 contains mandatory

requirements that apply to NRC licensees authorized to administer byproduct material or radiation to humans for medical use. These requirements also provide voluntary provisions for specialty boards to apply to have their certification processes recognized by the NRC so that their board certified individuals can use the certifications as proof of training and experience.

II. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 21st day of February 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,
NRC Clearance Officer,
Office of the Chief Information Officer.

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